



9/9/98

September 1, 1998

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Rexall Showcase International, Inc. located at 853 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 within the past 30 days marketed a dietary supplement bearing the following additional statement(s) on the label and/or in the labeling:

Meno•Essentials: Meno•Essentials [is] a unique dietary supplement formulated for women's special nutritional needs during perimenopause and menopause. [It] provides a unique combination of Novasoy brand of soy isoflavones, plus herbs and nutrients to support the changing nutritional needs of women experiencing perimenopause and menopause. Meno•Essentials nourishes the reproductive system, supports bone density and helps maintain healthy cholesterol levels. Meno•Essentials [is] a dietary supplement for women's changing nutritional needs during menopause.

The undersigned certifies that the information contained in this notice is complete and accurate and that Rexall Sundown, Inc. has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed

Sincerely,

Deborah Shur Trinker
Vice President of Regulatory Affairs
and Corporate Counsel

Enclosure

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